REMARKS

Applicants respectfully request entry of this amendment under 37 C.F.R. § 1.116 in order to place the application in condition for allowance or in better form for appeal.

Claims 11, 13, and 15, all the claims remaining, have been amended to recite "a purified" antibody or immunological complex. Support for this amendment can be found in the disclosure as a whole and, for example, at page 15, lines 30-35, where applicants describe how the disclosed peptides can be used to produce antibodies by "conventional" methods. Of course, one skilled in the art would understand that these antibodies are "purified" during the conventional methods for producing and screening them. In fact, methods to screen for monoclonal antibodies would seemingly include steps where the antibody and the immunological complex are, *inter alia*, purified from other antibodies, from the hybridoma cells, and from the hybridoma cell culture medium. No new matter enters by this amendment.

The only remaining rejection to claims 11, 13, and 15 is a rejection under 35 U.S.C. § 102(b). The final Office Action mailed January 3, 1996, states that the rejection is maintained because, allegedly, the claims are anticipated by Kalyanaraman *et al.* (Kalyanaraman) or Schupbach *et al.* (Schupbach) as evidenced by Arya *et al.* (Arya), Wong-Staal, and Cohen *et al.* (Cohen) for reasons of record. (Page 2 of the final Office Action.) Applicants respectfully traverse this rejection.

During examination, the Office must interpret claims only "as broadly as their terms reasonably allow." In re Zletz, 13 U.S.P.Q.2d 1320, 1322 (Fed. Cir. 1989). Applicants'

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specification disclosing an intended meaning also provides a basis for an appropriate interpretation. *Id.* In this case, therefore, applicants' above-noted disclosure in the specification (at page 15, lines 30-35) of the "conventional production and screening methods," as they relate to the claimed antibodies and immunological complexes comprising those antibodies, must be considered for a proper interpretation of the claims. When interpreted reasonably and in the context of applicants' disclosure, neither Kalyanaraman nor Schupbach can anticipate the presently claimed invention.

First, applicants will show below that applicants' disclosure does indeed define the term "purified" as now recited in the claims. Then, applicants will show that by a reasonable reading of the entire claim, in view of the teachings of applicants' disclosure, there is no support for the Office's current interpretation, where a drop of blood is equated to a purified antibody or immunological complex.

Applicants' Specification Directs One Skilled In The
Art To An Adequate Disclosure Of "Purified" As Now Recited

Initially, to clarify some of the written description support for applicants' present claims, an excerpt from page 15, line 25, through page 16, line 5, of the specification (as amended in the Preliminary Amendment filed March 5, 1993) is reproduced below.

> These polypeptides can be used as diagnostic tools, particularly for the detection of antibodies in biological media, particularly in sera or tissues of persons afflicted with pre-AIDS or AIDS, or simply carrying antibodies in the absence of any apparent disorders. Conversely, the different peptides according to this invention can be used themselves for the production of antibodies, preferably monoclonal antibodies specific of the different peptides respectively. For the production of hybridomas secreting said monoclonal antibodies, conventional production and

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screening methods are used. These monoclonal antibodies, which themselves are part of the invention, then provide very useful tools for the identification and even determination of relative proportions of the different polypeptides or proteins in biological samples, particularly human samples containing LAV or related viruses.

Applicants' claims should be considered in light of at least this excerpt, where applicants disclose numerous types of antibodies and immunological complexes to one skilled in the art. Applicants' description relating to the presently claimed antibodies and immunological complexes includes "diagnostic tools" and "conventional production and screening methods" and, thus, raises a volume of knowledge to one skilled in the art. Exemplary pieces of that knowledge are enclosed as Exhibits 1-4. Applicants will present below some of the relevant contents of these Exhibits.

Exhibit 1 (Hurn and Chantler, Methods in Enz., vol. 70: 104-142 (1980)) discusses methods for producing and purifying polyclonal and monoclonal antibodies, the preparation of columns where immunological complexes are formed, and the labeling of purified antibodies to ultimately detect immunological complexes. Especially relevant, pages 122-130 present methods for purifying antibodies from "nonspecific antisera" and purification techniques including ammonium sulfate precipitation, ion exchange chromatography, and affinity-chromatography. In addition, pages 134-135 discuss conjugated antibodies, where purified immunological complexes, in "gel diffusion or immunoelectrophoresis tests," are clearly involved.

Exhibit 2 (Galfre and Milstein, Methods in Enz., vol. 73: 3-46 (1981)) discusses the production, screening, and purification of monoclonal antibodies. Pages 41-45, in particular, indicate that purified monoclonal antibodies were a well known part of one's knowledge in

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the art. Furthermore, both purified immunological complexes and purified antibodies to immunological complexes are shown at pages 21-28, where the authors describe methods related to binding assays between the monoclonal antibodies and antigen.

Exhibit 3 (Higgins, Experientia, 36:889-890 (1980)) demonstrates that agarose gel purified immunological complexes were known and used in the art.

Finally, Exhibit 4 (Clark and Engvall, in "Enzyme Immunoassay," Maggio, ed., pages 167-179, CRC Press, 1980) discusses "immunoassays" and depicts and describes various purified antibodies and immunological complexes in those procedures.

Of course, these Exhibits comprise a small part of what one skilled in the art would have known about "immunoassays" and "conventional production and screening methods." An applicant preferably omits descriptions of well known techniques from a patent specification. Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1534, 3 U.S.P.Q.2d 1737, 1743 (Fed. Cir. 1987), *citing* Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986) *cert. denied*, 107 S. Ct. 1606 (1987). The present specification conforms to that practice. Thus, there was no need to include the known techniques in the art, such as those discussed in Exhibits 1-4.

From the understanding of one skilled in the art, the current claims reciting a "purified" antibody or immunological complex is properly disclosed. However, "purified" could not mean an antibody or immunological complex that is a mere needle prick away from coursing through the veins of a patient. Such an interpretation belies the knowledge of "immunoassays" and "methods for production and screening of antibodies." That knowledge

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appears to involve at least a washing, precipitation, or treating in a column along the way to becoming "purified."

The Office's Current Interpretation Of The Claims Is Improperly Broad

In Paper No. 15 (at page 5), the Office stated that the term "isolated" has been interpreted to mean "separated from the body." The final Office Action (at page 2) justifies this interpretation by alleging that the claims must be interpreted in their "broadest sense." But, as discussed above, even this "broadest sense" must be a reasonable interpretation and must take into consideration applicants' disclosure in the specification.

Also in Paper No. 15 (at page 5), the Office stated:

> Since the serum of infected individuals contains a wide spectrum of antibody specificities, and since ORFs of the HIV are expressed proteins, than inherently, the antibodies found in the serum of HIV infected individuals, would have specificities toward the ORFs as identified in the claims.

Thus, allegedly, the serum of an HIV-infected individual anticipates the claimed invention. However, in addition to the interpretation problems with respect to applicants' disclosure in the specification, the analysis and interpretation applied in this rejection would make the claims a "mere product of nature," which they clearly are not.

The purified antibodies and immunological complexes claimed simply cannot be properly interpreted as a drop of HIV-infected blood. Such a reading disregards the established law under 35 U.S.C. § 101, where a "mere product of nature" is unpatentable. Since the Office's current interpretation of the claimed invention would clearly be violative of 35 U.S.C. § 101, that interpretation cannot be reasonable. However, a "purified" antibody or

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immunological complex clearly establishes the "hand of man" in at least the purifying of the antibody or immunological complex.

It Is Only The Current, Improper Interpretation Of The Claims
That Can Support The Rejection Over Kalyanaraman Or Schupbach

That Kalyanaraman and Schupbach do not teach an antibody to any of the recited peptides does not appear to be disputed. The Office has only alleged that these documents evidence "specific antigens of varying molecular weights." (Paper No. 15 at page 5.) However, the Office has not pointed to any discussion of the recited peptides, as is required for a showing of anticipation.

The rejection is allegedly buttressed by the Arya, Wong-Staal, and Cohen documents. As these documents are not statutory "prior art," they are apparently used to show that Schupbach and Kalyanaraman inherently disclose the claimed invention. However, Arya, Wong-Staal, and Cohen cannot be read by one skilled in the art to show that Kalyanaraman or Schupbach actually purified the claimed antibodies or immunological complexes. The office has used these later published documents only to support the allegation that HIV-infected sera contains the claimed antibodies or immunological complexes. But, the later documents do not show, among other things, how Kalyanaraman or Schupbach could have possibly purified them. Without the peptides recited in the claims, Kalyanaraman and Schupbach could not even have identified the claimed antibodies or immunological complexes, much less purified them. Thus, it is only to the improper reading of the claims as allegedly encompassing naturally occurring antibodies that the assertions with respect to Arya, Wong-Staal, and Cohen apply.

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For these reasons, at least, applicants request withdrawal of this rejection as it may apply to applicants' amended claims.

If there are any fees due in connection with the filing of this Amendment, please charge such fees to our Deposit Account No. 06-0916. If an extension of time is required under 37 C.F.R. § 1.36 and not accounted for above, such an extension is respectfully requested and the fee should be charged to Deposit Account No. 06-0916.

Respectfully Submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Date: April 2, 1996

David J. Kulik
Registration No. 36,576

Encls: Exhibit 1 (Hurn et al., "Production of Reagent Antibodies")
Exhibit 2 (Galfrè et al., "Preparation of Monoclonal Antibodies:...")
Exhibit 3 (Higgins, "Immunogenicity of agarose-immobilized...")
Exhibit 4 (Clark et al., "Enzyme-Linked Immunosorbent Assay...")
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